BIOMATERIAL AND METHOD FOR ITS REALISATION

TECHNICAL FIELD OF THE INVENTION

The present invention regards a biomaterial useable in the medical field, having high characteristics of integration with the biological system in which it is interfaced, bioinductivity and bioconductivity characteristics.

The present invention further regards a method for obtaining a biomaterial having high characteristics of integration with the biological system in which it is interfaced, bioinductivity and of bioconductivity characteristics.

DESCRIPTION OF RELATED ART

Ceramic and/or polymeric biomaterials substantially used for fixing prosthesis or as bone substitutes are currently the most commonly used in the field of biomaterials, in particular biomaterials useable in the orthopaedic and surgery field, for filling cavities or lacunae of various origin and type.

Such polymeric biomaterial includes, for example, acrylic bone cement, possibly made up of polymethylmethacrylate (PMMA) and methylmethacrylate (MMA), and absorbable cements, the latter used in cases where the support function that they are required to perform is limited over time.

Ceramic biomaterials are, usually, polycrystalline aggregates constituted by an ordered series of elements joined together by strong bonds. Such ceramic biomaterials can be bioactive, i.e., induce—in the biological tissues—a response upon the occurrence of chemical and physical processes on the biomaterial/biological tissue interface.

Active ceramic biomaterials include, for example, calcium phosphate salts (CPC), among which the most commonly used are hydroxyapatite (HA), alpha-tricalcium phosphate (α-TCP) and beta-tricalcium phosphate (β-TCP), which have a high biocompatibility and an ideal bioconductivity.

However such materials reveal some drawbacks.

Acrylic cement has optimal mechanical performance which guarantees functional implants even lasting twenty years. However, it does not develop a chemical bond with the bone tissue and the mechanical resistance thereof is essentially based on the friction on the interface with the prosthesis and the bone; furthermore, it cannot be absorbed.

Though biocompatible and at least partly absorbable, calcium phosphate cements instead, reveal poor mechanical resistance.

A method for producing a biocompatible polymeric/ceramic composite material with a predetermined porosity, designed and determined previously, is also known.

Such method comprises a first step of preparing a suspension of a ceramic biomaterial in water, a second step in which a compact of ceramic biomaterial containing the desired amount of water is obtained from this suspension and a third step of mixing such compact with a polymeric material and/or with a liquid monomer.

The composite material obtained from the method described in the abovementioned patent application, as well as other biomaterials based on polymeric matrix and particles which can be dissolved in a stage subsequent to the preparation one, for example calcium phosphate, combine the characteristics of biocompatibility and absorbability, for example of calcium phosphate, with the mechanical resistance of polymeric cement.

However, the methods for obtaining such materials are extremely complex and difficult and they have not lead to any commercial product up to date; furthermore, though potentially osteoinductive and osteoconductive, the polymeric/ceramic materials allow bone colonization solely in the most external and surface area thereof and they are not capable of obtaining a complete in-depth colonization of the bone.

It is known that a biomaterial of suitable porosity, when arranged in a vital bone tissue, is invaded by such tissue only if the cavities have—in the biomaterial—a dimension larger than 100 microns.

On the contrary, when a non-porous biomaterial is arranged in a bone tissue, a fibrous tissue cover, referred to as fibrous sheath, is generated at the interface between the biomaterial and the bone tissue.

The formation of such fibrous sheath insulates the biomaterial from the bone, prevents integration and regeneration thereof and it is thus harmful, also due to the fact that in such a manner such sheath constitutes an interruption or discontinuity between the cement and the bone and hinders the possibility of bearing high mechanical loads.

In an attempt to counter the occurrence of such fibrous sheath, the most standard procedure is that of using biomaterials which have surface cavities adapted to receive the new-formation of the bone tissue. The newly-formed bone is implanted into such porosity thus improving the adhesion between the biomaterial and the bone tissue.

The solutions used currently and described above, however, did not obtain the expected tissue regeneration and implantation, as visible in FIG. **1**, due to the fact that the spread porosity does not have cavities larger than 100 microns.

For example, some materials, such as ceramic materials, due to a largely spread porosity, conferred by large intercommunicating cavities with dimension comprised between 200 and 500 microns, are capable of obtaining the tissue regeneration inside the material but to the detriment of mechanical resistance. Thus, the use of such biomaterials is limited to a bone filler not subjected to direct loads. Actually, such materials are used as cranial prosthesis, which however, if subjected to impacts or loads, can break without guaranteeing suitable resistance characteristics required even in such part of the human body.

The previously described biomaterials do not meet all the requirements suitable for supporting and possibly quickening such tissue growth.

Thus, there arises the need of providing a biomaterial which, alongside having good mechanical resistance, is capable of allowing the regeneration of the tissue with which it is to be interfaced, for use in the orthopaedic field, dental field etc. Such tissue is in particular the bone tissue.

Actually, tissue regeneration requires a suitable support, conferred by the biomaterial, which, as previously indicated, requires having conductive and inductive characteristics with respect to the tissue to be regenerated.

SUMMARY OF THE INVENTION

Thus, the object of the present invention is that of improving the prior art.

Within such technical task, the present invention aims at providing a biomaterial adapted to be interfaced with organic tissues without creating adverse reactions in the tissue or at systemic level.

Another object of the present invention is that of providing a biomaterial having bioinductive and bioconductive characteristics, in particular osteoinductive and osteoconductive. A further object of the present invention is that of providing a biomaterial adapted to allow the colonization—therein—of